

AMENDMENTS TO THE CLAIMS

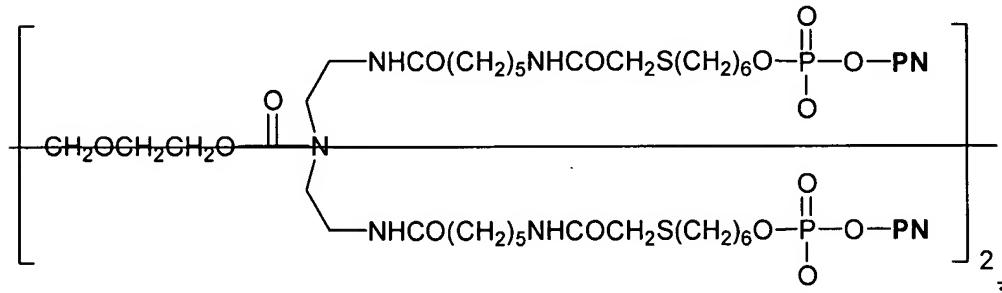
This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-38 (cancelled)

Claim 39 (currently amended): A method of stabilizing or improving the health-related quality of life ~~in or of~~ of a human individual with systemic lupus erythematosus (SLE), comprising the steps of:

(a) assessing the health-related quality of life of the human individual with SLE;
~~(a)(b) selecting an individual for receiving or continuing to receive to receive treatment based on the individual's need for a stabilized or improved health-related quality of life; and~~
~~(b)(c) administering to the selected individual an effective amount of a dsDNA epitope, which specifically binds to an anti-dsDNA antibody, wherein the amount administered is an amount effective to stabilize or improve the health-related quality of life of to the selected individual, and wherein administration of the dsDNA epitope results in a sustained reduction of at least about 10% in the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and~~

~~wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula~~



~~wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),~~

~~the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.~~

Claims 40-60 (cancelled)

Claim 61 (new): The method of claim 39, wherein the stabilization or improvement of health-related quality of life is a stabilization or improvement in one or more aspects of health-related quality of life selected from the group consisting of limitations in physical activities because of health problems, limitations in social functioning because of physical or emotional problems, limitations in work or other usual activities because of physical health problems, bodily pain, general mental health, limitations in work or other usual activities because of emotional problems, vitality, and general health perception.

Claim 62 (new): A method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of:

- (a) assessing the health-related quality of life of a human individual with SLE who has been receiving treatment with a dsDNA epitope, which specifically binds to an anti-dsDNA antibody;
- (b) selecting an individual for continuing to receive treatment with the dsDNA epitope based on the individual's health-related quality of life; and
- (c) administering to the selected individual an amount of the dsDNA epitope effective to stabilize or improve the health-related quality of life of the selected individual,
wherein administration of the dsDNA epitope results in a sustained reduction of at least about 10% in the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month.

Claim 63 (new): The method of claim 62, wherein the stabilization or improvement of health-related quality of life is a stabilization or improvement in one or more aspects of health-related quality of life selected from the group consisting of limitations in physical activities because of health problems, limitations in social functioning because of physical or emotional problems, limitations in work or other usual activities because of physical health problems, bodily pain, general mental health, limitations in work or other usual activities because of emotional problems, vitality, and general health perception.

Claim 64 (new): A method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of:

- (a) assessing the stabilization or improvement in the health-related quality of life of a human individual with SLE who has been receiving treatment with a dsDNA epitope, which specifically binds to an anti-dsDNA antibody;
- (b) selecting an individual for continuing to receive treatment with the dsDNA epitope based on the individual's stabilization or improvement in health-related quality of life; and
- (c) administering to the selected individual an amount of the dsDNA epitope effective to stabilize or improve the health-related quality of life of the selected individual,
wherein administration of the dsDNA epitope results in a sustained reduction of at least about 10% in the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month.

Claim 65 (new): The method of claim 64, wherein the stabilization or improvement of health-related quality of life is a stabilization or improvement in one or more aspects of health-related quality of life selected from the group consisting of limitations in physical activities because of health problems, limitations in social functioning because of physical or emotional problems, limitations in work or other usual activities because of physical health problems, bodily pain, general mental health, limitations in work or other usual activities because of emotional problems, vitality, and general health perception.

Claim 66 (new): A method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of:

- (a) assessing the health-related quality of life of a human individual with SLE who has been receiving treatment with a dsDNA epitope, which specifically binds to an anti-dsDNA antibody;
- (b) selecting an individual for treatment with an adjusted dosage of the dsDNA epitope based on the individual's health-related quality of life; and

(c) administering to the selected individual an adjusted dosage of the dsDNA epitope, wherein the adjusted dosage is effective to stabilize or improve the health-related quality of life of the selected individual,

wherein administration of the dsDNA epitope results in a sustained reduction of at least about 10% in the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, thereby stabilizing or improving the individual's health-related quality of life.

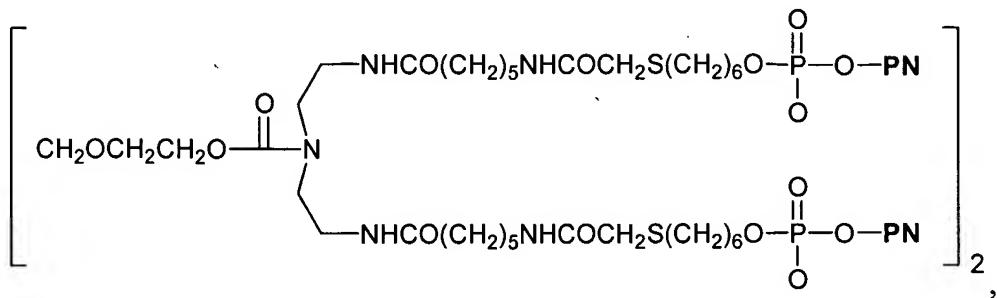
Claim 67 (new): The method of claim 66, wherein the stabilization or improvement of health-related quality of life is a stabilization or improvement in one or more aspects of health-related quality of life selected from the group consisting of limitations in physical activities because of health problems, limitations in social functioning because of physical or emotional problems, limitations in work or other usual activities because of physical health problems, bodily pain, general mental health, limitations in work or other usual activities because of emotional problems, vitality, and general health perception.

Claim 68 (new): The method of claim 39, 62, 64, or 66, wherein the dsDNA epitope comprises a double-stranded polynucleotide 5'-TGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) in combination with its complementary strand, or one of the single-stranded polynucleotides 5'-TGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) or 5'-CACACACACACACACACA-3' (SEQ ID NO:2).

Claim 69 (new): The method of claim 68, wherein the dsDNA epitope is administered in the form of a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more double-stranded DNA (dsDNA) epitopes that specifically bind to an anti-dsDNA antibody from the individual.

Claim 70 (new): The method of claim 39, 62, 64, or 66, wherein the dsDNA epitope is administered in the form of a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more double-stranded DNA (dsDNA) epitopes that specifically bind to an anti-dsDNA antibody from the individual.

Claim 71 (new): The method of claim 70, wherein the conjugate is a compound of the formula



wherein PN is $(\text{CA})_{10}\bullet(\text{TG})_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)).

Claim 72 (new): The method of claim 71, wherein the conjugate is administered to the individual in a dose of about 5 mg to about 100 mg of the conjugate per kg of the individual.

Claim 73 (new): The method of claim 71, wherein the conjugate is administered in a dose of about 200 mg to about 500 mg to the individual.

Claim 74 (new): The method of claim 39, 62, 64, or 66, which is a method of improving the health-related quality of life of an individual with systemic lupus erythematosus (SLE), wherein the administration of the dsDNA epitope results in an improvement in the individual's health-related quality of life.

Claim 75 (new): The method of claim 39, 62, 64, or 66, wherein the effective amount of the dsDNA epitope is administered to the individual for a period of more than about 16 weeks.

Claim 76 (new): The method of claim 39, 62, 64, or 66, wherein the sustained reduction is at least about 20% below baseline.

Claim 77 (new): The method of claim 76, wherein the sustained reduction is at least about 30% below baseline.

Claim 78 (new): The method of claim 39, 62, 64, or 66, wherein the sustained reduction is maintained for more than about 16 weeks.

Claim 79 (new): The method of claim 78, wherein the sustained reduction is maintained for more than about 24 weeks.

Claim 80 (new): The method of claim 79, wherein the sustained reduction is maintained for at least about 1 year.

Claim 81 (new): The method of claim 61, 63, 65, or 67, wherein the stabilization or improvement in the individual's health-related quality of life is detectable by the Medical Outcome Survey Short Form 36 (SF-36).

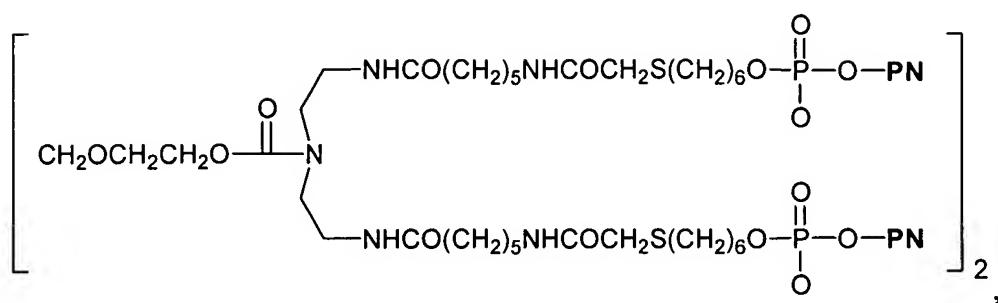
Claim 82 (new): The method of claim 75, wherein the effective amount of the dsDNA epitope is administered to the individual for a period of more than about 24 weeks.

Claim 83 (new): A method of stabilizing or improving the health-related quality of life of a human individual with SLE comprising the steps of:

- (a) assessing the health-related quality of life of the human individual with SLE;
- (b) selecting the individual to receive treatment based on the individual's need for a stabilized or improved health-related quality of life; and
- (c) administering to the selected individual an amount of a dsDNA epitope effective to stabilize or improve the health-related quality of life of the selected individual,

wherein administration of the dsDNA epitope results in a sustained reduction in the level of circulating anti-dsDNA antibodies in the individual of at least 10% that is maintained for at least about one month, and

wherein the dsDNA epitope is administered in the form of a conjugate of the formula



wherein PN is $(\text{CA})_{10}\bullet(\text{TG})_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)).